

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *et al.*  
*ex rel.* JULIE LONG,

Plaintiffs,

V.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

**PLAINTIFF’S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL  
DEFENDANT TO PROVIDE COMPLETE ANSWERS TO INTERROGATORIES  
15, 20 & 22 AND TO SUPPLEMENT ITS INITIAL DISCLOSURES**

Plaintiff-relator Julie Long submits this memorandum of law in support of her motion under Federal Rule of Civil Procedure 37(a) and Local Rule 37.1 requesting the Court to order defendant Janssen Biotech, Inc., to provide complete answers to Interrogatories 20 and 22 and Amended Interrogatory 15 and to supplement its initial disclosures within seven days.

The interrogatories ask Janssen to disclose the support for three of its main affirmative defenses so that Plaintiff can obtain discovery concerning the defenses. Despite its representations in response to Plaintiff's February 16, 2022 motion to compel answers to Interrogatories 20 and 22, Janssen is refusing to provide this critical information to which Plaintiff is unquestionably entitled. Plaintiff has also requested that Janssen supplement its incomplete initial disclosures so that she can obtain necessary discovery concerning Janssen's defenses. As part of its ongoing attempt to conceal the identities of key witnesses and withhold relevant documents, Janssen, here again, is refusing to identify the individuals who are likely to have discoverable information that the company may use to support its defenses and the

documents in its possession that it may use to support its defenses. There is no justification for Janssen continuing to withhold and delay providing this important and basic discovery.

On multiple occasions, Plaintiff has attempted in good faith to resolve these discovery disputes before seeking the Court's intervention (both before filing this motion as well as the February 16 motion). Most recently, Plaintiff had a telephone conference with Janssen's counsel to review the issues. The conference, which took place on April 20 and was attended by attorneys Leopold, Preston, and Martin on behalf of Plaintiff and attorneys Tremont and Cobb on behalf of Janssen, lasted over an hour. During the conference, Janssen refused to agree to provide complete answers to the three interrogatories or to supplement its initial disclosures.

## **I. FACTUAL & PROCEDURAL BACKGROUND**

From approximately 2001 through 2020, Janssen regularly provided (via a large team of employees called "Area Business Specialists" (or "ABSs") and outside consultants) a wide variety of practice management and infusion business support and consulting services to select rheumatology and gastroenterology physician practices nationwide free of charge to help them open, operate, and grow their in-office infusion suite ("IOI") businesses and, in turn, induce them to prescribe and infuse Remicade and Simponi ARIA.<sup>1</sup> These practice management and infusion business support and consulting services are collectively referred to herein as "the IOI Support." Plaintiff alleges that by providing this remuneration to induce doctors to prescribe and administer Remicade and Simponi ARIA infusions to patients, many of whom were insured by Medicare, Janssen violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and the False

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<sup>1</sup> Trying to make the free practice management and infusion business services at issue appear like they merely furnished clinical and billing information about Remicade and Simponi ARIA, Janssen misleadingly refers to the free services at issue as "medical education," "patient support," and "product support" services.

Claims Act (“FCA”), 31 U.S.C. §§ 3729 *et seq.*

On November 18, 2020, Janssen filed its answer to Plaintiff’s Second Amended Complaint, asserting several affirmative defenses. *See* ECF 83.

This motion was filed due to Janssen’s refusal to (1) provide complete answers to three interrogatories—15 (as amended), 20, and 22—that specify the support and witnesses for three of its main affirmative defenses and (2) update its initial disclosures to identify the individuals who likely have discoverable information that it may use to support its defenses as well as the documents it may use to support its defenses.

Janssen’s incomplete initial disclosures were served on December 22, 2020. A copy is provided herewith as Exhibit 1.

Janssen’s incomplete answer to Amended Interrogatory 15 was served on June 22, 2021. A copy of the incomplete answer can be viewed at ECF 279-8 (filed under seal).

Plaintiff propounded Interrogatories 20 and 22 on January 3, 2022. On February 4, Janssen served objections to the interrogatories but provided no answers. Consequently, on February 16, Plaintiff moved to compel answers. *See* ECF 278. Janssen filed its response to the motion on March 3, in which the company said that it would provide the answers. *See* ECF 294. Janssen provided answers on March 17. However, the answers are materially incomplete. A copy of Janssen’s supplemental objections and responses to Interrogatories 20 and 22 is submitted herewith as Exhibit 2.

For the reasons stated below, the Court should order Janssen to provide complete answers to Interrogatories 20 and 22 and Amended Interrogatory 15 and should further order the company to supplement its initial disclosures.

## II. ARGUMENT

### A. Janssen's Objections Lack Merit

None of the objections Janssen asserted in response to Interrogatories 20 and 22 and Amended Interrogatory 15 have merit or relieve it from providing the information at issue in this motion. These are the same objections Janssen asserted in its earlier response to Interrogatories 20 and 22 and are addressed in Plaintiff's February 16 motion to compel (ECF 278). In the event Janssen raises any of the objections in opposing this motion, Plaintiff incorporates by reference the arguments in her February 16 motion (ECF 278) that correspond to the objection(s).

### B. Janssen's Answers To Interrogatories 20 & 22 Are Materially Incomplete

Janssen has asserted the following affirmative defenses, among others:

**AFFIRMATIVE DEFENSE 8:** Relator's claims for relief are barred, in whole or in part, because any false claims that Janssen allegedly submitted or caused to be submitted and any false record or statement that Janssen allegedly made, used, or caused to be made or used to get a claim paid were not done knowingly.

**AFFIRMATIVE DEFENSE 14:** Relator's claims for relief are barred, in whole or in part, because any and all actions taken by Janssen with respect to any of the matters alleged by Relator were taken in good faith and in accordance with established industry practice.

Def.'s Answer to 2d Am. Compl. (ECF 83) at 52 (¶¶ 8 & 14).

Interrogatories are typically the most appropriate method for discovering the facts that form the basis of affirmative defenses. *See, e.g., Fidelity Mgmt. & Research Co. v. Actuate Corp.*, 275 F.R.D. 63, 64 (D. Mass. 2011); *Trustees of Boston Univ. v. Everlight Electronics Co. Ltd.*, Civ. No. 12-11935-PBS, 2014 WL 5786492, at \*4-5 (D. Mass. Sep. 2014). As part of her effort to discover more detail and the underlying support for Janssen's contention in Affirmative Defense 14 that it had a good faith belief that providing the IOI Support did not violate the AKS or FCA and to obtain information about the individuals who have knowledge concerning the contention, Plaintiff served Interrogatory 20:

**INTERROGATORY 20:** State whether you contend that when you provided each of the various types of IOI Support and IOI Support Programs that you had a good faith belief that your actions did not violate any law, statute, or regulation, and if so set forth all facts, documents, and evidence that support your contention and identify the witnesses who have knowledge concerning your contention.

Similarly, to discover the details and underlying support for Janssen's contention in Affirmative Defense 8 that it did not "knowingly" cause the alleged false claims to be submitted to Medicare and to obtain information about the individuals who have knowledge concerning that contention, Plaintiff propounded Interrogatory 22:

**INTERROGATORY 22:** In Affirmative Defense No. 8 of your Answer to the Second Amended Complaint you contend that "any false claims that Janssen allegedly submitted or caused to be submitted and any false record or statement that Janssen allegedly made, used, or caused to be made or used to get a claim paid were not done knowingly." Set forth all facts, documents, and evidence that support your contention and identify the witnesses who have knowledge concerning your contention.

After Plaintiff moved to compel answers on February 16, 2022 (ECF 278), Janssen provided partial answers to Interrogatories 20 and 22 on March 17, 2022. However, Janssen is required to provide full answers. *See* Fed. R. Civ. P. 33(b)(3); Local Rule 26.5(c)(8). As is evident from the answers, while generally asserting that it "reasonably believed" that providing the IOI Support was lawful, the company does not identify (1) the witnesses who have knowledge concerning its beliefs, (2) the reviews, assessments, analyses, opinions, and advice that contributed and gave rise to the company's asserted beliefs, (3) when those assessments, analyses, determinations, interpretations, and advice were received or took place, or (4) the documents and evidence that support its contentions:

**ANSWER TO INTERROGATORY 20 (EXCLUDING OBJECTIONS<sup>2</sup>):**

Notwithstanding the foregoing general and specific objections, Janssen responds that, *at the time the product support services were provided, and through the present, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute*

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<sup>2</sup> Janssen's full response to this interrogatory, including its objections, is at Exhibit 2 at 7-9.

**(“AKS”), 42 U.S.C. § 1320a–7b, and False Claims Act (“FCA”), 31 U.S.C. §§ 3728–3733.** The legality of the programs is supported by the publicly available guidance materials from relevant government agencies, which have consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also* Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013). [Emphasis added.]

Furthermore, on multiple occasions, the Office of Inspector General, U.S. Department of Health and Human Services (“OIG”) has found that the AKS is not implicated by comparable programs and services. *See* OIG Advisory Opinions and judicial decisions cited in Janssen’s Motion to Dismiss Plaintiff’s Second Amended Complaint (“Janssen’s Motion to Dismiss”), ECF No. 59, at 6, 8–12.

Janssen further responds that its good faith and reasonable efforts to comply with the AKS and FCA are demonstrated by practices and standards of its Health Care Compliance (“HCC”) department applicable to ABS engagement with physician practices. Tom Cornely served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices. Janssen has searched for and is producing relevant, nonprivileged guidance and policies that can be located after a reasonable search.

Janssen further responds that its good faith and reasonable efforts to comply with the AKS and FCA are demonstrated by the fact that medical education and patient support resources go through an approval process by Janssen’s Promotional Review Committee (“PRC”) or its equivalent. Janssen is searching for and producing accessible and relevant PRC records.

Janssen further responds that between approximately 2003 and 2011, the Department of Justice (“DOJ”) and OIG conducted an investigation that involved, among other topics, the medical education and patient support services challenged by Plaintiff, including services that Plaintiff defines as IOI Support Programs. As part of this investigation, DOJ and OIG reviewed and analyzed the patient support services that Relator now claims are kickbacks. The investigation was closed, and the DOJ and OIG did not take any action against Janssen, despite knowing about the patient support programs. Given the Government’s extensive knowledge of Janssen’s medical education and patient support services, including services that Plaintiff defines as IOI Support Programs, and the fact that the Government has not taken any action against Janssen, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA. Thus, Relator cannot demonstrate falsity, scienter, intent, or materiality.

**ANSWER TO INTERROGATORY 22 (EXCLUDING OBJECTIONS<sup>3</sup>):**

Janssen further responds that, *at the time the product support services were provided, and through the present, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA.* The legality of the programs is supported by the publicly available guidance materials from relevant government agencies, which consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also* Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013). Furthermore, on multiple occasions, the OIG has found that the AKS is not implicated by comparable programs and services. *See* OIG Advisory Opinions and judicial decisions cited in Janssen's Motion to Dismiss, 6, 8-12. [Emphasis added.]

Janssen further responds that its HCC department established practices and standards applicable to ABS engagement with physician practices. Tom Cornely served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices. Janssen searched for and is producing accessible and relevant, non-privileged guidance and policies that can be located after a reasonable search.

Janssen further responds that medical education and patient support resources go through an approval process by Janssen's PRC or its equivalent. Janssen is searching for and producing accessible and relevant PRC records.

Janssen further responds that between approximately 2003 and 2011, the DOJ and OIG conducted an investigation that involved, among other topics, the medical education and patient support services challenged by Plaintiff, including services that Plaintiff defines as IOI Support Programs. As part of this investigation, DOJ and OIG reviewed and analyzed the patient support services that Relator now claims are kickbacks. The investigation was closed, and the DOJ and OIG did not take any action against Janssen, despite knowing about the patient support programs. Given the Government's extensive knowledge of Janssen's medical education and patient support services, including services that Plaintiff defines as IOI Support Programs, and the fact that the Government has not taken any action against Janssen, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA. Thus, Relator cannot demonstrate falsity, scienter, intent, or materiality.

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<sup>3</sup> Janssen's full response to this interrogatory, including its objections, is at Exhibit 2 at 15-16.

***Who are the witnesses who have knowledge concerning the asserted beliefs?***

The drug company asserts in these answers that it “reasonably believed” that providing the IOI Support was lawful. Yet it does not identify the officers, employees, or agents whose interpretations, opinions, or advice contributed and gave rise to the company’s asserted beliefs or that the company relied upon and adopted. Nor does Janssen identify the officers, employees, or agents who were involved in the assessments, analyses, deliberations, and consultations that led to the company’s asserted beliefs. For instance, who reviewed and advised management concerning the Department of Health & Human Services Office of Inspector General’s (“OIG”) Compliance Program Guidance and advisory opinions that Janssen references in the partial interrogatory answers? Who analyzed and advised management that the government’s inaction following an unspecified investigation meant that it was lawful to provide the IOI Support at issue, as Janssen contends in the partial answers?<sup>4</sup>

***What reviews, assessments, and analyses contributed and gave rise to the asserted beliefs?***

Likewise, the partial answers do not identify the specific reviews, assessments, and analyses concerning the legality of providing the IOI Support that contributed and gave rise to Janssen’s asserted beliefs. This information is necessary to discover the truthfulness of Janssen’s asserted beliefs, to determine whether the purported reviews and analyses were based on full and complete disclosure of the facts, and the reliability of the determinations, interpretations, and advice from these reviews, assessments, and analyses.

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<sup>4</sup> Tellingly, Janssen had not previously disclosed the existence of this unspecified investigation, let alone provide notice that it is one of the bases for its asserted belief that providing the IOI Support was lawful.

***When did the reviews, assessments, and analyses that contributed and gave rise to Janssen's asserted beliefs take place?***

Additionally, the partial answers do not disclose the material information of when the alleged reviews, assessments, and analyses that led to the company's asserted beliefs that providing the IOI Support was lawful occurred. Janssen provided several different types of IOI Support over more than 15 years. When during this period did it receive the interpretations, advice, and opinions that it relied upon in reaching its asserted beliefs? And when, if ever, did it review or revisit the analyses and assessments?

***What documents and evidence support the asserted beliefs?***

The incomplete answers likewise do not identify the documents reflecting or concerning the reviews, assessments, analyses, interpretations, and advice that contributed to or gave rise to Janssen's asserted beliefs that providing the IOI Support was lawful.

***What "practices and standards" were in place that caused Janssen to believe that providing the IOI Support did not violate the AKS and FCA?***

The incomplete answers do not identify the "practices and standards applicable to ABS engagement with physician practices" that caused Janssen to believe it was lawful to provide the IOI Support. Nor do the answers identify when such practices and standards were implemented or who implemented them.

***None of the requested information and documents are privileged.***

Interrogatories 20 and 22 request information about the support for Janssen's allegations asserted as part of *affirmative defenses* – allegations that voluntarily and directly place into issue Janssen's beliefs as well as the reasonableness of such beliefs. Moreover, Janssen has advised Plaintiff and the Court that it is not asserting a reliance upon counsel defense. *See* Def.'s Mem. of Law in Opp'n to Mot. Compel Disclosure of All Legal Opinions and Analyses (ECF 272).

And of course, analyses, reviews, and assessments conducted by non-lawyers and non-lawyers' interpretations, opinions, and advice are not privileged.

**C. Janssen's Answer To Interrogatory 15 Is Materially Incomplete**

Janssen also asserts as an affirmative defense that "Relator's claims for relief are barred, in whole or in part, because Janssen reasonably interpreted the statutes and regulations at issue in the [Second Amended Complaint]." Def.'s Answer to 2d Am. Compl. (ECF 83) at 52 (¶13). To discover the facts that form the basis for this affirmative defense, Plaintiff propounded Amended Interrogatory 15:

**AMENDED INTERROGATORY 15:** State all the facts that you believe support your contention in Affirmative Defense No. 13 of your Answer to the Second Amended Complaint that "Janssen reasonably interpreted the statutes and regulations at issue in the SAC," including identifying all persons who performed the analyses that form the basis for Affirmative Defense No. 13 and when such analyses were performed.

Here again, the answer Janssen provided is materially deficient and noncompliant with Federal Rule of Civil Procedure 33(b)(3). While asserting that it reasonably interpreted the AKS, FCA, and OIG's guidance and advisory opinions, Janssen failed to provide the requested material information about (1) who performed the analyses that formed the basis for the asserted contention, and (2) when those analyses were performed and reviewed:

**RESPONSE (EXCLUDING OBJECTIONS)<sup>5</sup>:** Notwithstanding the foregoing general and specific objections, Janssen's reasonable interpretation of governing statutes and regulations is supported by the publicly available guidance materials from HHS, which have consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also* Medicare and State Health Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013). Furthermore, on multiple occasions, HHS-OIG has found that the Anti-Kickback Statute is not implicated by comparable product support programs and services. *See* OIG Advisory Opinions and judicial decisions cited in Janssen's Motion to Dismiss, ECF No. 59, at 6, 8-12. These

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<sup>5</sup> Janssen's full response to this interrogatory, including its objections, is at ECF 279-8 (filed under seal) at 13-14.

materials and the underlying statutes and regulations speak for themselves.

Janssen further responds that its HCC department was involved in establishing recommended practices and standards for ABS engagement with physician practices. Tom Cornely served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices. Additionally, legal counsel for Janssen, including Freddy Jimenez, have provided privileged legal advice concerning medical education and patient support services provided by ABSs.

***Whose interpretations did the company rely upon and when were those interpretations made?***

The incomplete answer does not identify the officers, employees, or agents whose interpretations of the AKS, FCA, and OIG guidance materials and advisory opinions the company relied upon and adopted. Additionally, the answer does not provide when the alleged reviews, analyses, and interpretations were made or when they were subsequently adopted and relied upon by Janssen. This discovery is necessary to be able to test the veracity of Janssen's asserted contention and determine the competency of the individuals who made the interpretations and the reasonableness of Janssen's reliance upon those interpretations.

***None of the requested information and documents are privileged.***

Here again, Interrogatory 15 requests information concerning the support for Janssen's allegations made as part of an *affirmative defense* – allegations that voluntarily and directly place into issue Janssen's beliefs and the reasonableness of its asserted beliefs. And, once again, Janssen has represented to Plaintiff and the Court that it is not asserting a reliance upon counsel defense. This highly relevant information is not privileged.

**D. Janssen's Initial Disclosures Are Materially Incomplete**

Janssen's current initial disclosures required under Federal Rule of Civil Procedure 26(a)(1)(e) identify ***just three individuals*** who are likely to have discoverable information that the company may use to support its defenses. *See* Exhibit 1 at 2. The current initial disclosures

do not indicate that any of the three employees was involved in analyzing or assessing statutes or determining whether providing the IOI Support complied with the AKS and FCA.

Under Rule 26(e)(1)(A), “[a] party who has made a disclosure under Rule 26(a) ... must supplement or correct its disclosure ... in a timely manner if the party learns that in some material respect the disclosure ... is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.” Fed. R. Civ. P. 26(e)(1)(A). Plaintiff requested that Janssen update its initial disclosures so that she will know which individuals are likely to have discoverable information that Janssen may use to support its defenses, including the affirmative defenses discussed in this motion. Janssen refused to update its initial disclosures falsely claiming that Plaintiff should be able to determine the witnesses it is likely to use to support its defenses from the discovery already provided. As evidenced by the incomplete interrogatory responses discussed above, Janssen’s contention is false. Likewise, Janssen has not otherwise informed Plaintiff concerning the individuals whose interpretations, analyses, and advice contributed or gave rise to its beliefs that providing the IOI Support was lawful.

Despite asserting numerous defenses, including the affirmative defenses discussed herein in which the company asserts general allegations that for more than 15 years it reasonably believed that providing the IOI Support was lawful and did not violate the AKS and FCA, Janssen is refusing to identify the individuals and provide the analyses at the center of its affirmative defenses. There is no justification for Janssen withholding this fundamental discovery.

### **III. CONCLUSION**

For the foregoing reasons, the Court should order Janssen to provide within seven days

complete answers to Interrogatories 20 and 22 and Amended Interrogatory 15 and to supplement its initial disclosures in accordance with Federal Rule of Civil Procedure 26(e)(1)(A).

Dated: April 25, 2022

Respectfully submitted,

/s/ Casey M. Preston

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***Counsel for Plaintiff Relator Julie Long***

**CERTIFICATE OF SERVICE**

I hereby certify on this 25<sup>th</sup> day of April, 2022, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Casey M. Preston

Casey M. Preston (admitted pro hac vice)